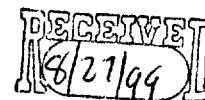




6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

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August 18, 1999



Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson brand name bearing the following statement(s) on the label and/or in the labeling:

Kava Kava: [It] promotes a calming sense of well-being. With the increasing stress of modern life, more and more people are relying on Kava Kava as a natural, effective way to promote relaxation. For centuries, Pacific islanders have used Kava Kava for its unique ability to evoke a feeling of calm contentment. Thompson's Kava Kava Advanced Formula combines Kava Kava extract with an Advanced Formula blend of the whole herbs Hops, Chamomile and Passionflower to help promote a calming and soothing sense of well-being.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in cursive script, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

97S-0162

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